

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

SOUTHEASTERN PENNSYLVANIA  
TRANSPORTATION AUTHORITY, JANE  
DOE, and JOHN DOE, individually and on  
behalf of all others similarly situated,

Plaintiffs,

v.

GILEAD SCIENCES, INC.,

Defendant.

Case No. 2:14-cv-06978-SD

The Honorable Stewart R. Dalzell

**ORDER**

**AND NOW**, on this \_\_\_\_\_ day of \_\_\_\_\_, 2015, upon consideration of Defendant Gilead Sciences, Inc.'s 12(b)(6) Motion to Dismiss Plaintiffs' First Amended Complaint, together with any Reply thereto, it is hereby **ORDERED** that the Motion is **GRANTED**. It is **FURTHER ORDERED** that Plaintiffs' First Amended Complaint is **DISMISSED WITH PREJUDICE**. The Clerk shall close the case.

BY THE COURT:

\_\_\_\_\_  
Stewart R. Dalzell, United States District Judge

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**DEFENDANT GILEAD SCIENCES, INC.'S  
12(b)(6) MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT**

Defendant, Gilead Sciences, Inc. moves to dismiss Plaintiffs' First Amended Complaint in its entirety and with prejudice, pursuant to Federal Rule of Civil Procedure 12(b)(6) and Local Rule 7.1. Defendant incorporates in full its Memorandum In Support of Defendant's 12(b)(6) Motion to Dismiss Plaintiffs' First Amended Complaint, filed contemporaneously herewith.

Dated March 9, 2015

Respectfully Submitted,

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Case No. 2:14-cv-06978-SD

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**MEMORANDUM IN SUPPORT OF DEFENDANT'S 12(b)(6) MOTION  
TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT**

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## **INTRODUCTION**

Defendant Gilead Sciences, Inc. (“Gilead”) developed and brought to market Sovaldi® and Harvoni®, two breakthrough therapies for patients suffering from the hepatitis C virus (“HCV”). These two drugs cure this devastating and sometimes fatal disease at unprecedented rates, and do so faster and with fewer adverse side effects than any drug previously available. The Amended Complaint recognizes these facts, but complains about the prices for these life-saving drugs.

In their original complaint, Plaintiffs alleged that Gilead’s pricing violated Section 2 of the Sherman Act, 15 U.S.C. § 2. But, as a matter of black letter law, an allegedly high price – even a purported “monopoly” price – does not violate Section 2. *Pac. Bell Tel. Co. v. Linkline Commc’ns, Inc.*, 555 U.S. 438, 447-48 (2009). Indeed, the law is clear that a successful company’s right to set its own prices “is not only not unlawful; it is an important element of the free-market system.” *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004).

Recognizing this, in the Amended Complaint Plaintiffs abandon their Sherman Act claims, and instead assert a grab-bag of alternate theories under which Gilead purportedly has an obligation to charge some unspecified lower price for its patented, breakthrough drugs. None of Plaintiffs’ theories comes close to stating a claim:

1. Patient Protection and Affordable Care Act (“ACA”). Plaintiffs’ primary theory in the Amended Complaint appears to be a novel claim that Gilead “discriminates” against patients on the basis of their having HCV because of the prices it charges for its HCV treatments. This makes no sense. Gilead does not offer HCV treatments at lower prices to consumers who are *not* suffering from HCV. Indeed, consumers who are not suffering from HCV do not seek to buy

HCV treatments in the first place. There is simply no legal basis whatsoever for Plaintiffs' ACA claim.

2. California Unfair Competition. Plaintiffs next claim that Gilead's prices violate the California Unfair Competition Law ("UCL"). This claim is equally insufficient. As a threshold matter, federal patent law preempts any attempt to use state law to regulate the prices of patented pharmaceuticals like those at issue here, and this is fatal to all of Plaintiffs' state law claims. In addition, Plaintiffs' UCL claim fails for the independent reason that California law does not authorize courts to convert themselves into regulatory bodies and begin choosing "fair" prices for products. In the one prior case in which a plaintiff came close to making such an absurd claim, it was soundly rejected.

3. Unjust Enrichment. Unjust enrichment is not an independent cause of action under California law, and this claim fails along with Plaintiffs' other deficient state law claims.

4. Duty of Good Faith. Plaintiffs' claim that Gilead's pricing breaches a contractual duty of good faith also fails. Among other flaws, this claim depends on the nonsensical premise that compliance with contractual pricing terms constitutes bad faith.

In sum, the Amended Complaint is just as deficient as the original. Gilead respectfully requests that the Amended Complaint be dismissed in its entirety with prejudice. *Alston v. Kean Univ.*, 549 F. App'x 86, 88-89 (3d Cir. 2013) (affirming dismissal of amended complaint without leave to amend).

### **STATEMENT OF FACTS**

In January 2012, Gilead invested \$11 billion to acquire sofosbuvir, a potential treatment for HCV that was in the development process. AC ¶ 29. At the time, sofosbuvir was in what the Food and Drug Administration ("FDA") calls "Phase II" trials, and was just about to begin the most costly and perhaps most uncertain phase of its clinical development, namely large-scale

“Phase III” clinical trials to test the drug for safety and efficacy. *Id.* The FDA requires that companies successfully complete Phase III trials as a condition for approval for sale of a pharmaceutical product in the United States. *Id.*; *see also, e.g., FDA Drug Approval Process*, Food and Drug Administration.<sup>1</sup>

Since acquiring sofosbuvir in 2012, Gilead has continued to invest in developing the product. AC ¶ 29. Following nearly two additional years of work and investment, Gilead brought its first sofosbuvir product, Sovaldi, to market in December 2013. AC ¶ 3. And Gilead subsequently introduced its next generation “combination” sofosbuvir product, Harvoni, in 2014. *Id.*

Sovaldi and Harvoni represent a breakthrough in treatment for patients suffering from HCV. *See* AC ¶ 2 (“Both Sovaldi and Harvoni are, by all accounts, remarkably effective drugs.”). The products provide very high cure rates, and do so after a relatively short course of treatment and with minimal side effects. *Id.* Sovaldi and Harvoni have been in great demand since their launch. AC ¶¶ 3, 6. These therapies provide an effective treatment for a disease that Plaintiffs themselves have described as an “epidemic” that has killed more people in the U.S. since 2007 than HIV. *See, e.g.,* AC ¶ 27 (noting that prior treatments “cured only about half” of patients treated and often had “debilitating side effects,” and that HCV could lead to liver failure and death); AC ¶ 2 (noting that Gilead’s HCV treatments cure more than 90% of patients, with relatively minor side effects).

Gilead has numerous U.S. patents covering its innovations in Sovaldi and Harvoni: The Amended Complaint alleges that the FDA Orange Book lists five granted U.S. patents covering Sovaldi and ten granted patents covering Harvoni. AC ¶ 36. While Plaintiffs allege that Gilead

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<sup>1</sup> Available at <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm295473.htm>. “[I]t is appropriate for a court to take judicial notice of the FDA’s published guidance to industry.” *Abely v. Aeterna Zentaris Inc.*, No. 12 Civ. 4711, 2013 WL 2399869, at \*21 (S.D.N.Y. May 29, 2013) (collecting cases).

has challenged *Merck's* patents in the HCV space, AC ¶ 109, and that Gilead has faced challenges that sales of sofosbuvir infringe certain *Idenix* patents, AC ¶¶ 112, 114, Plaintiffs *do not allege* that there have been *any* challenges to the validity of Gilead's Orange Book-listed U.S. patents.

Since the introduction of Sovaldi, there have been further developments in the treatment of HCV. In December 2014, a competitor to Gilead, AbbVie, received FDA approval for its own HCV therapy, Viekira Pak, which it offered at a list price that was marginally lower than the list price for Sovaldi. AC ¶ 48. Plaintiffs further allege that, since then, there has been continued competition for sales of HCV treatments that has led manufacturers to offer discounts off of the list price. *See* AC ¶¶ 51-59 (noting various rebate deals since December 19, 2014 that have resulted in significant price reductions).

Plaintiffs acknowledge that Gilead provides discounts to a number of purchasers, for example the Department of Veterans Affairs. AC ¶ 41. And Plaintiffs concede that Gilead offers a Patient Assistance Program, through which it provides HCV treatments to eligible patients at no cost. AC ¶¶ 21, 74-75 (noting existence of Patient Assistance Program but complaining that the program involves burdensome paperwork, such as income verification forms). But Plaintiffs nonetheless allege that Gilead's prices for Sovaldi and Harvoni are "exorbitant." AC ¶ 44.

Plaintiffs Jane and John Doe are individuals who have been diagnosed with HCV. AC ¶¶ 21, 22. Both of these plaintiffs have medical insurance. *Id.* Neither has paid for or taken Gilead's HCV treatments. *Id.* In both cases, their insurance companies declined to cover the treatment. *Id.* Specifically, Plaintiff Jane Doe alleges that she could not obtain Sovaldi because (1) the drug "was not an available drug on her formulary," (2) she was ineligible for Gilead's patient assistance program "because she had private insurance," and (3) she would not be able to

afford to purchase the drug on her own. AC ¶ 21. Similarly, Plaintiff John Doe alleges he was unable to obtain Sovaldi because “his insurance company ultimately denied coverage.” AC ¶ 22.

Plaintiff SEPTA is a transportation authority that alleges that it has reimbursed or paid for certain members of its employee benefit plan to receive one of Gilead’s HCV treatments. AC ¶ 20. The Amended Complaint does not allege whether any of the named plaintiffs sought to obtain other HCV treatments, such as AbbVie’s Viekira Pak.

### **LEGAL STANDARD**

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), “a complaint must contain sufficient factual matter . . . to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The Supreme Court has long held that “a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed.” *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 528 n.17 (1983). “[O]nly by taking care to require allegations” with sufficient heft can courts “avoid the potentially enormous expense of discovery in cases with no ‘reasonably founded hope’” of success. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007) (citation omitted).

A complaint should be dismissed with prejudice where amendment would be futile. *See, e.g., Dimeo v. Max*, 433 F. Supp. 2d 523, 532 (E.D. Pa. 2006) (Dalzell, J.), *aff’d*, 248 F. App’x 280 (3d Cir. 2007) (affirming dismissal of original complaint with prejudice due to futility of amendment); *Knellinger v. York St. Prop. Dev., LP*, No. CIV.A. 14-4712, 2014 WL 5758007, at \*9 (E.D. Pa. Nov. 6, 2014) (Dalzell, J.) (denying leave to amend where the complaint’s deficiencies were “not due to lack of factual specificity”). Dismissal with prejudice due to futility is particularly appropriate where the relief sought is simply not authorized under existing law. *See, e.g., Tillio v. Spiess*, 441 F. App’x 109, 110 (3d Cir. 2011) (affirming dismissal with



prejudice where there was no “factual or legal basis” for the claim). As this Court explained in denying leave to amend in a prior case, a plaintiff “cannot change the applicable law with more artful pleading.” *Alvarez v. Ins. Co. of N. Am.*, No. CIV A 06-4326, 2006 WL 3702641, at \*4 (E.D. Pa. Dec. 12, 2006) (Dalzell, J.), *aff’d*, 313 F. App’x 465 (3d Cir. 2008).

Dismissal with prejudice is also appropriate when dealing with amended complaints. A plaintiff need not be given an opportunity “to take a third bite at this apple.” *Johnson-Lloyd v. Vocational Rehab. Office*, No. CIV. A. 92-5082, 1993 WL 293894, at \*2 (E.D. Pa. July 29, 1993) (Dalzell, J.); *see also, e.g., Rubenstein v. Dovenmuehle Mortg., Inc.*, No. CIV. A. 09-721, 2009 WL 3467769, at \*11 (E.D. Pa. Oct. 28, 2009) (Dalzell, J.) (dismissing amended complaint with prejudice); *Capell v. Pulte Mortg. L.L.C.*, No. CIV.A. 07-1901, 2008 WL 269521, at \*1 (E.D. Pa. Jan. 14, 2008) (Dalzell, J.) (same); *Kerrigan v. Otsuka Am. Pharm., Inc.*, No. 12-4346, 2012 WL 5380663, at \*4 (E.D. Pa. Nov. 1, 2012) (McLaughlin, J.) (dismissing with prejudice where “the plaintiff would not be able to re-plead in a way that would state a viable claim”).

## **ARGUMENT**

### **I. Plaintiffs Fail to State a Claim Under the Affordable Care Act**

Plaintiffs assert that Gilead’s pricing violates the anti-discrimination provisions of Section 1557 of the ACA. This section provides that “an individual shall not, on [the basis of any protected ground], be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance . . . .” 42 U.S.C. § 18116. Protected grounds, in turn, include race, color, national origin, sex, age, and disability.<sup>2</sup>

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<sup>2</sup> See 42 U.S.C. § 2000d (race, color, and national origin); 20 U.S.C. § 1681(a) (sex); 42 U.S.C. § 6101 (age); 29 U.S.C. § 794(a) (disability).

In the present case, Plaintiffs assert that Gilead engaged in discrimination against individuals on the basis of their *having HCV*, which Plaintiffs argue is a disability under Section 504 of the Rehabilitation Act. AC ¶ 132 (asserting that “[p]ersons infected with Hepatitis C have a ‘disability’ within the meaning of section 504 of the Rehabilitation Act”). There are numerous flaws in Plaintiffs’ argument including that: (a) Plaintiffs do not actually allege acts showing discrimination on the basis of HCV; (b) a neutral price is not discriminatory; and (c) in any event, simply having HCV is not a disability.

**A. Plaintiffs Fail to Allege Discrimination *on the Basis of HCV***

Plaintiffs allege that Gilead offers its HCV treatments at a discount to certain customers, including the Federal Bureau of Prisons and the U.S. Department of Veterans Affairs. AC ¶ 41. Plaintiffs further allege that Gilead has offered discounts to some pharmaceutical benefit managers. AC ¶ 47. Plaintiffs acknowledge that Gilead has a Patient Assistance Program through which Gilead provides its HCV treatments at no cost to eligible patients who lack insurance. AC ¶¶ 21, 74-75. And Plaintiffs allege that Gilead provides HCV treatments to HCV patients abroad, in particular in developing nations, at a substantial discount. *See, e.g.*, AC ¶ 40.

Plaintiffs allege that all of these discounts are designed to provide Sovaldi and Harvoni at lower prices *to patients who are suffering from HCV*. *See, e.g.*, AC ¶ 42 (alleging that the Department of Veterans Affairs is the largest provider of HCV care in the United States). Plaintiffs *do not allege* that Gilead offers its HCV treatments at lower prices to consumers *who do not have HCV*. That is, Plaintiffs do not attempt to allege that Gilead is actually discriminating in price *on the basis of whether or not an individual has HCV*. This, in itself, is fatal to Plaintiffs’ claim of discrimination.

## **B. A Neutral Price Is Not Discriminatory**

Plaintiffs’ real claim seems to be that the price for Gilead’s HCV treatments (and, presumably, those of AbbVie, which Plaintiffs allege are very similar) are simply too high across the board. *See, e.g.*, AC ¶ 44 (asserting that prices even to the Department of Veterans Affairs are “exorbitant”). In suggesting that a pharmaceutical company “discriminates” against *all* potential consumers of its drug by allegedly setting its prices too high, Plaintiffs seek to transform the anti-discrimination provisions of the ACA into a massive and unspecified price-regulation statute. This stretches the statutory language well beyond the breaking point.

At the most basic level, federal anti-discrimination laws seek to allow a market to work free from bias. They do not dictate the economic terms on which markets will work. Anti-discrimination laws in the labor market, for example, ensure that workers in a protected group have an equal opportunity to compete for employment – that women, for example, have an equal opportunity to become firefighters even if some people had preconceptions that only men could do the job. Anti-discrimination laws do *not* dictate the starting salary that a fire department must offer to all firefighters.

Plaintiffs are fundamentally and improperly seeking to use the anti-discrimination provision in the ACA to demand sweeping judicial price regulation. This would require dramatically re-writing the law. If, at some point in the future, Congress were to decide to substitute the judgment of the courts for that of the market and the agencies that currently regulate how companies make drugs and medical devices available to the market, history shows that Congress would offer careful guidance on how this should be done.<sup>3</sup>

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<sup>3</sup> For example, in 1986, Congress enacted the Emergency Medical Treatment & Labor Act (EMTALA) to ensure public access to emergency services regardless of ability to pay. The EMTALA imposes very specific obligations on Medicare-participating hospitals that offer emergency services to provide identified types of care, which cannot be refused on the basis of inability to pay. *See* 42 U.S.C. § 1395dd (requiring screening and treatment for specified

Plaintiffs' theory is so counter to the principles behind anti-discrimination statutes that there are few examples of a plaintiff even trying to pursue such a claim. But, when alleged high prices to everyone has been advanced as a purported basis of discriminatory action, the notion has been firmly rejected. For example, the Fourth Circuit considered and rejected such a theory in *Williams v. 5300 Columbia Pike Corp.*, 103 F.3d 122, 1996 WL 690064 (4th Cir. 1996) (per curiam) (unpublished opinion). The plaintiffs in that case, African-American and disabled residents of a cooperative association, argued that the association's plan to convert their dwelling units to condominiums excluded them, in violation of the anti-discrimination provisions of the Fair Housing Act, because they lacked the money necessary for the conversion. The Fourth Circuit rejected this claim because the alleged injury was **"solely the product of a facially neutral price (e.g., a price that does not vary depending on one's race, handicap, or other status protected by the Fair Housing Act)"** and thus could not constitute discrimination:

[T]he Fair Housing Act is not so expansive that it would require sales or rentals of residences to those who concede that they are unable to pay the price faced by all other buyers or leasers. **The Fair Housing Act does not purport to grapple with the truism that, all things being equal, those with money are better off than those without it.**

*Id.* at \*3 (emphasis added).

The Fourth Circuit's decision is the correct one: A theory that an alleged high price violates anti-discrimination laws because it excludes those unable or unwilling to pay would

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emergency medical situations); *see also, e.g., Jackson v. E. Bay Hosp.*, 246 F.3d 1248, 1255 (9th Cir. 2001) (noting that, under the clear terms of the statute, the EMTALA is carefully limited to "an 'emergency medical condition,' that is manifested by 'acute' and 'severe' symptoms") (citing *Eberhardt v. City of Los Angeles*, 62 F.3d 1253, 1258 (9th Cir. 1995); *del Carmen Guadalupe v. Negron Agosto*, 299 F.3d 15, 19 (1st Cir. 2002) (similar). Moreover, if Congress ever were to craft such legislation, it would also need to take into account the effects of its new price control legislation on the incentives to innovate embodied in United States patent law. *Cf., e.g., United States v. Fausto*, 484 U.S. 439, 453 (1988) ("[I]t can be strongly presumed that Congress will specifically address language on the statute books that it wishes to change."); *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 138-44 (2001) (similar in context of patent laws).

have no limiting principle. *Any price will exclude those who lack the means or willingness to pay. Taken to its logical conclusion, the claim that it is discriminatory to set prices that are inaccessible to some is a mandate that a product be available at or below cost to all. And, in a world where pharmaceutical development is risky and costly, such a rule would be a radical departure from our free market system, which seeks to “safeguard the incentive to innovate” and “induce[] risk taking that produces innovation and economic growth.”* *Trinko*, 540 U.S. at 407.

Plaintiffs’ proposal is not only unsupported by the law, it is inappropriate as a matter of policy: “Courts are ill suited ‘to act as central planners, identifying the proper price, quantity, and other terms of dealing.’” *Linkline*, 555 U.S. at 452. As the Supreme Court has explained: “[H]ow is a judge or jury to determine a ‘fair price?’ . . . How can the court determine this price without examining costs and demands, indeed without acting like a rate-setting regulatory agency, the rate-setting proceedings of which often last for several years?” *Id.* at 454 (quoting *Town of Concord, Mass. v. Boston Edison Co.*, 915 F.2d 17, 25 (1st Cir. 1990) (Breyer, C.J)). As the Sixth Circuit put it, for a court to try to determine whether a particular price is reasonable would be to “set sail on a sea of doubt.” *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 284 (6th Cir. 1898) (Taft, J.). Thankfully, the ACA requires no such result.

### **C. “Having HCV” Is Not a Disability**

Plaintiffs’ claim that Gilead engages in discrimination in violation of the ACA fails for the independent reason that simply having HCV is not a disability under § 504 of the Rehabilitation Act, *see* AC ¶ 132. A physical or mental impairment can qualify as a “disability” under § 504 only if it substantially interferes with at least one major life activity. *See* 29 U.S.C. § 705(20)(B); 42 U.S.C. § 12102(1)(A). But it is an unavoidable fact that millions of Americans with HCV do not even know that they are infected, much less have physical or mental impairment rising to the level of interfering with major life activities. In fact, Plaintiffs

themselves concede this point. *See, e.g.*, AC ¶ 24 (alleging that an estimated 2.7 to 5.2 million people in the United States have HCV, and that “50% to 75% of those who have Hepatitis C do not know they are infected.”). And, indeed, the purported named plaintiffs here do not allege that their HCV infection has interfered with their own major life activities in any way. To the contrary, they allege merely that they were diagnosed with HCV. AC ¶¶ 21-22.

But it is well established that “not every illness is considered a disability, even if the disease is life-threatening or ultimately terminal.” *Ellis v. Mohenis Servs. Inc.*, No. CIV. A. 96-6307, 1998 WL 564478, at \*3, 7 (E.D. Pa. Aug. 24, 1998) (holding that plaintiff with HCV was not disabled under the Americans with Disabilities Act (“ADA”)).<sup>4</sup> Indeed, numerous courts have held that HCV alone “is not enough to qualify as a disability.” *Amos v. Corr. Med. Servs., Inc.*, No. CIV.A. 06-CV-1892, 2009 WL 1884142, at \*6 (D.N.J. June 30, 2009) (collecting cases). *See also, e.g., Shultz v. Potter*, 142 F. App’x 598, 599-600 (3d Cir. 2005) (citation omitted) (mere fact that plaintiff was diagnosed with diabetes, a potentially serious disease, did not render her disabled under the Rehabilitation Act).

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In sum, Plaintiffs’ ACA claim fails because they have not shown any discrimination on the basis of a protected condition. The ACA provides no basis for their demand that this Court pick a new price for Sovaldi and Harvoni, and this claim should be dismissed.

## **II. Plaintiffs Fail to State a Claim Under State Law**

Plaintiffs assert state law claims for unfair competition, unjust enrichment, and breach of the contractual duty of good faith and fair dealing. Plaintiffs assert that the unfair competition claim is brought under California law, and fail to specify a state as to the other claims. For purposes of this motion, we treat all of these claims as having been brought under California law.

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<sup>4</sup> The Rehabilitation Act incorporates the ADA’s definition of “disability.” *See* 29 U.S.C. § 705(20)(B); 42 U.S.C. § 12102(1)(A).

Plaintiffs’ state law claims fail for numerous reasons, including because: (a) they are all preempted by federal patent law; (b) a firm’s unilateral pricing decisions are neither unfair nor unlawful; (c) there is no cause of action in California for unjust enrichment; and (d) as to Plaintiffs’ contract claim, they fail to allege the most basic elements of this cause of action.

**A. All of Plaintiffs’ State Law Claims Are Preempted by Federal Patent Law**

Plaintiffs concede that the products at issue here, Sovaldi and Harvoni, are patent-protected pharmaceuticals. AC ¶ 36. Plaintiffs ask this Court to use state law to determine the worth of these products and set a “fair” price for them. But, when it comes to patented products, Congress is “the promulgator of patent policy.” *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1373 (Fed. Cir. 2007). As the Federal Circuit has explained: “The Patent Act creates an incentive for innovation. The economic rewards during the period of exclusivity are the carrot. . . . Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace.” *Biotechnology*, 496 F.3d at 1372 (quoting *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995)).<sup>5</sup>

*Biotechnology* has particular relevance here. The case concerned a District of Columbia law known as the “Prescription Drug Excessive Pricing Act,” which purported to regulate drug prices by prohibiting the sale of “any patented drug . . . for an excessive price.” *Id.* at 1365. The Federal Circuit struck down this attempt to regulate drug prices. As the court explained, “[b]y penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—the District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs.” *Id.* at 1374. As the court noted, the federal patent system “reflects the result of Congress’s deliberations” regarding “the proper

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<sup>5</sup> “The Federal Circuit court has sole appellate responsibility for the development of patent law, which includes determining whether and to what extent patent law preempts or conflicts with other causes of action . . . .” *IMCS, Inc. v. D.P. Tech. Corp.*, 264 F. Supp. 2d 193, 196 n.5 (E.D. Pa. 2003) (citation and quotation marks omitted).

balance between innovators' profit and consumer access to medication.” *Id.* at 1373-74. The Excessive Pricing Act would have impermissibly “change[d] federal patent policy” by “shift[ing] the benefits of a patented invention from inventors to consumers.” *Id.*

Accordingly, the Federal Circuit affirmed the decision of the district court holding that the Excessive Pricing Act was preempted by the federal patent laws and affirmed the district court's injunction against the law's enforcement. As the court explained, the Excessive Pricing Act was plainly an impermissible “obstacle to the federal patent law's balance of objectives as established by Congress.” *Id.* at 1374. Given that it is beyond the authority of a legislature to determine that a pharmaceutical price is “excessive,” it is *a fortiori* beyond the authority of a court applying a vague state law of general application to achieve the same result.

Just as in *Biotechnology*, Plaintiffs' complaint here implicates an enduring “tension between the desire to freely exploit the full potential of our inventive resources and the need to create an incentive to deploy those resources.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989). But the Patent Clause of the United States Constitution entrusts the task of balancing those prerogatives to Congress, not to state law. U.S. Const. art. I, § 8; *Bonito Boats*, 489 U.S. at 152 (holding that state statute was preempted by the federal patent laws because “[w]here it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess”); *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) (noting that “state laws that conflict with federal law are without effect”) (quotation marks and citation omitted); *see also, e.g., Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 716 (1984) (holding that state statute was preempted by federal copyright laws).

Any recovery by the Plaintiffs in this case would operate in precisely the same manner as the Excessive Pricing Act would have, had it been allowed to take effect: it would shift benefits of the patented product from inventors to consumers and thereby “re-balance the statutory



framework of rewards and incentives” for inventions and discoveries. *Biotechnology*, 496 F.3d at 1374. The only difference is that, here, Plaintiffs lack the benefit of any state law (even an invalid one) on which to hang their claims. Because the relief Plaintiffs seek is inconsistent with the federal patent laws, Plaintiffs’ state law claims should be dismissed.

**B. Independent Pricing Decisions Are Not Unfair or Unlawful Under the California Unfair Competition Law**

The California UCL prohibits the commission of “any unlawful, unfair or fraudulent business act or practice.” Cal. Bus. & Prof. Code § 17200, *et seq.* Plaintiffs claim that Gilead’s pricing violates the UCL because it is both “unlawful” and “unfair.” But both of these avenues require a violation of some law, or an incipient violation of the antitrust laws or its policies. Plaintiffs no longer attempt to assert any federal antitrust claims, and they have no valid claim under any other law. Accordingly, they cannot state a claim under the UCL.

Not Unlawful. “A violation of another law is a predicate for stating a cause of action under the UCL’s unlawful prong.” *Graham v. Bank of Am., N.A.*, 172 Cal. Rptr. 3d 218, 231 (Ct. App. 2014) (citation and quotation marks omitted). “Where a plaintiff cannot state a claim under the ‘borrowed’ law, she cannot state a UCL claim either.” *Silcox v. State Farm Mut. Auto. Ins. Co.*, No. 14cv2345, 2014 WL 7335741, at \*5 (S.D. Cal. Dec. 22, 2014) (citations omitted). Here, Plaintiffs have not stated a claim under the ACA for the reasons noted above.

Plaintiffs also no longer allege a violation of the antitrust laws, nor could they. It is settled law that “[t]he price of [a patented drug] cannot violate the Sherman Act: a patent holder is entitled to charge whatever the traffic will bear.” *Schor v. Abbott Labs.*, 457 F.3d 608, 610 (7th Cir. 2006) (Easterbrook, J.). *See also, e.g., Trinko*, 540 U.S. at 407 (“charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system” and “induces risk taking that produces innovation and economic growth”); *Linkline*, 555 U.S. at 447-48 (“charging monopoly prices does not violate § 2.”); *Trace X Chem., Inc. v. Canadian Indus.*,

*Ltd.*, 738 F.2d 261, 268 (8th Cir. 1984) (“[S]etting a high price is not in itself anti-competitive . . . but rather is the normal, rational response of a business . . . seeking to maximize profits, sales or revenues.”) (quotation marks and citation omitted).<sup>6</sup>

Without a violation of the antitrust laws or any other statute, Plaintiffs have not properly alleged that Gilead’s pricing was unlawful. Thus, to the extent that Plaintiffs are claiming a violation of the UCL because Gilead’s pricing is “unlawful,” this claim must be dismissed. *See Graham*, 172 Cal. Rptr. 3d at 231-32 (upholding dismissal for failure to sufficiently allege a predicate violation of law); *Leong v. Square Enix of Am. Holdings, Inc.*, No. CV 09-4484, 2010 WL 1641364, at \*7 (C.D. Cal. Apr. 20, 2010), *aff’d*, 462 F. App’x 688 (9th Cir. 2011) (claim under “unlawful” prong of UCL fails where underlying allegations of illegal conduct were dismissed).

Not Unfair. Plaintiffs also assert that Gilead’s pricing violates the UCL because it is “unfair.” “Although the unfair competition law’s scope is sweeping, it is not unlimited. Courts may not simply impose their own notions of the day as to what is fair or unfair.” *Cel-Tech Commc’ns, Inc. v. Los Angeles Cellular Tel. Co.*, 973 P.2d 527, 541 (Cal. 1999). Yet Plaintiffs in this case would have this Court do just that – they ask this Court to create an amorphous standard for when a firm’s pricing is “fair.”

This request should be rejected. There is no precedent for using the UCL as a rate-regulation statute. *See, e.g., Kent v. Avis Rent A Car Sys. LLC*, No. G044884, 2012 WL 831561, at \*9 (Cal. Ct. App. Mar. 13, 2012) (unpublished opinion) (“We have uncovered no UCL cases in which a court has found a charge to be ‘excessive’ in the absence of deceptive or misleading

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<sup>6</sup> *See also, e.g., Anticompetitive Practices*, U.S. Fed. Trade Comm’n, [ftc.gov/enforcement/anticompetitive-practices](http://ftc.gov/enforcement/anticompetitive-practices) (“It is important to note that it is not illegal for a company to have a monopoly, to charge ‘high prices,’ or to try to achieve a monopoly position by aggressive methods.”); *Working Party No. 2 on Competition and Regulation*, U.S. Dep’t of Justice, October 17, 2011, ¶ 10, *available at* [justice.gov/atr/public/international/278823.pdf](http://justice.gov/atr/public/international/278823.pdf) (“[A]ny remedial action . . . to lower prices could easily discourage entry and investment and harm consumers.”).

information about it”). Plaintiffs’ allegations fail to meet the established standard for alleging an “unfair” act under the UCL. To determine whether an act is “unfair” in violation of the UCL, the courts generally apply a “tethering” test, under which a plaintiff must “show the defendant’s conduct is tethered to an underlying constitutional, statutory or regulatory provision, or that it threatens an incipient violation of an antitrust law, or violates the policy or spirit of an antitrust law.” *Graham*, 172 Cal. Rptr. 3d at 233-34 (quotation marks and citations omitted).<sup>7</sup> For the reasons noted above, Plaintiffs have not properly alleged a violation of any provision of law, nor have they alleged an incipient violation of the antitrust laws or policies. *Trinko*, 540 U.S. at 407 (“The opportunity to charge monopoly prices—at least for a short period—is what attracts ‘business acumen’ in the first place; it induces risk taking that produces innovation and economic growth.”).<sup>8</sup>

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<sup>7</sup> In *Cel-Tech*, the California Supreme Court held that “any finding of unfairness to competitors under section 17200 [must] be tethered to some legislatively declared policy or proof of some actual or threatened impact on competition.” 973 P.2d at 544. The *Cel-Tech* Court limited its holding to competitor cases, but went on to expressly disapprove of cases that had applied an older “balancing test” in consumer cases because the test was “too amorphous” and “provide[d] too little guidance to courts and businesses.” 973 P.2d at 543. A third test, based on the FTC Act, has also been disapproved of by a number of courts. See, e.g., *Lozano v. AT&T Wireless Servs., Inc.*, 504 F.3d 718, 736 (9th Cir. 2007) (refusing to apply FTC test in absence of clear instruction from California Supreme Court). The weight of the post-*Cel-Tech* authority thus supports application of the tethering test in consumer actions as well.

<sup>8</sup> Even under the older balancing standard, it is clear that Plaintiffs’ UCL claim fails. See *Bardin v. Daimlerchrysler Corp.*, 39 Cal. Rptr. 3d 634, 643 (Ct. App. 2006) (affirming dismissal because auto manufacturer’s practice of using cheaper parts, allegedly “to earn excessive profits,” was not unfair: “increasing profits and gaining market share” does not “violate public policy”); *Fabozzi v. StubHub, Inc.*, No. C-11-4385, 2012 WL 506330, at \*7 (N.D. Cal. Feb. 15, 2012) (dismissing with prejudice UCL claim based on excessive ticket prices and explaining that “[s]o long as purchasers of tickets are getting exactly what they paid for—genuine tickets—at a price they are willing to pay, it is hard to understand how such a transaction could be deemed unfair”); *Spiegler v. Home Depot U.S.A., Inc.*, 552 F. Supp. 2d 1036, 1046 (C.D. Cal. 2008) (dismissing the plaintiffs’ UCL claims because “the UCL cannot be used to rewrite their contracts or to determine whether the terms of their contracts are fair”); *Jackson v. Atl. Savings of Am.*, No. C 13-05755, 2014 WL 4802879, at \*9 (N.D. Cal. Sept. 26, 2014) (dismissing complaint for lack of conduct meeting the first element of the old unfairness test); *Lazo v. Bank of Am., N.A.*, No. 12-762, 2012 WL 1831577, at \*12 (N.D. Cal. May 18, 2012) (holding that

Not surprisingly, when claims involving “unfair pricing” are pursued under the UCL, they are firmly rejected. *Boris v. Wal-Mart Stores, Inc.*, 35 F. Supp. 3d 1163 (C.D. Cal. 2014). In *Boris*, the plaintiffs argued that Wal-Mart acted unfairly when it packaged the same active pharmaceutical ingredient as a headache remedy and as a migraine remedy, and then priced the two packages differently. The court dismissed this claim because “price regulation is a political question beyond the judiciary’s authority” under the UCL. 35 F. Supp. 3d at 1172. As then-District Court Judge, now California Court of Appeals Justice Collins explained:

[t]aken to its logical conclusion, **Plaintiffs’ claim requires the judiciary to make pricing decisions**, such as ruling that pharmacologically identical drugs must be the same price or may have only a limited price differential, or imposing liability for differential pricing on a necessarily unpredictable case-by-case basis. To state this result is to demonstrate that it is untenable: **price regulation is a political question beyond the judiciary’s authority.**

*Id.* at 1171-72 (emphasis added).

Other courts have reached the same conclusion, dismissing purported UCL claims that threaten to drag the courts into complex economic policy because determining the best economic policy “is primarily a legislative and not a judicial function.” *Desert Healthcare Dist. v. PacifiCare, FHP, Inc.*, 114 Cal. Rptr. 2d 623, 634 (Ct. App. 2001) (rejecting request for court intervention because the healthcare finance industry is “an economic arena that courts are ill-equipped to meddle in”). Indeed, courts have declined to wade into judging “fairness” in cases concerning issues of far less complexity and significance than the pricing of prescription drugs at issue here. *See, e.g., Wolfe v. State Farm Fire & Cas. Ins. Co.*, 53 Cal. Rptr. 2d 878, 885-87 (Ct. App. 1996) (homeowners insurance); *Winans by and through Moulton v. Emeritus Corp.*, No. 13-cv-03962, 2014 WL 970177, at \*6-7 (N.D. Cal. Mar. 5, 2014) (care facility staffing).

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plaintiffs failed to state a claim despite conclusory allegations that defendant’s actions were “immoral, unethical, oppressive, unscrupulous and/or substantially injurious”).

This rule is the right one: If the price charged for a good or service could be the basis of a UCL unfair pricing claim, there would be no limit to the scope of the UCL; any transaction could be retroactively challenged as unfair by a customer who wished he had paid less or prospectively challenged by a customer who never bought the product at all. The courts would overflow with plaintiffs bringing UCL claims challenging all manner of prices. *Accord, e.g., Linkline*, 555 U.S. at 452 (“Courts are ill suited ‘to act as central planners, identifying the proper price, quantity, and other terms of dealing.’”).

No Standing. Plaintiffs’ UCL claim fails for the independent reason that Plaintiffs lack the injury in fact necessary for standing under the statute. Private actions for relief under the UCL may be prosecuted only “by a person who has suffered injury in fact and has lost money or property as a result of the unfair competition.” Cal. Bus. & Prof. Code § 17204. “The plain import of this is that a plaintiff . . . must demonstrate some form of economic injury.” *Kwikset Corp. v. Superior Court*, 246 P.3d 877, 885 (Cal. 2011). At a minimum, the provision “eliminate[s] standing for those who have not engaged in any business dealings with would-be defendants.” *Id.* at 899.

Plaintiffs allege that John Doe and Jane Doe did not buy or use any of Gilead’s HCV treatments. *See* AC ¶¶ 21-22. Because the Does did not purchase Gilead’s products, they lack standing under the UCL and their claims must be dismissed. *See Carrea v. Dreyer’s Grand Ice Cream, Inc.*, No. C 10-01044, 2011 WL 159380, at \*3 (N.D. Cal. Jan. 10, 2011), *aff’d*, 475 F. App’x 113 (9th Cir. 2012) (dismissing claim for lack of standing because plaintiff did not “allege[] that he purchased Defendant’s . . . products or otherwise suffered any injury or lost money or property with respect to those products”).

Plaintiff SEPTA, likewise, cannot meet the standing requirement. SEPTA alleges that it indirectly paid for Defendant’s HCV treatments. But SEPTA has obtained the benefit of its

bargain. *See Johnson v. Mitsubishi Digital Elecs. Am., Inc.*, 365 F. App'x 830, 832 (9th Cir. 2010). The UCL claim rejected in *Johnson* was substantially stronger than SEPTA's claim here: In *Johnson*, the plaintiff purchased a television and brought a UCL claim alleging that the manufacturer "fooled him into purchasing a television that was not as advanced as he believed it was." *Johnson v. Mitsubishi Digital Elecs. Am., Inc.*, 578 F. Supp. 2d 1229, 1232 (C.D. Cal. 2008). The court rejected the claims, explaining that the plaintiff "still watches the television," which the plaintiff conceded works "great," and that the plaintiff tacitly admitted that "he bought the best television on the market at the time." *Id.* The Ninth Circuit explained that "[i]f one gets the benefit of his bargain, he has no standing under the UCL." *Johnson*, 365 F. App'x at 832. Here, on the face of the Amended Complaint SEPTA concedes that the products it bought work extremely well. AC ¶ 2. Because SEPTA received the benefit of its bargain, its UCL claim should be dismissed. *See also, e.g., Peterson v. Cellco P'ship*, 80 Cal. Rptr. 3d 316, 318, 322 (Ct. App. 2008) (rejecting UCL claim by insurance purchasers because they "received the benefit of their bargain, having obtained the bargained for insurance at the bargained for price")

**C. Plaintiffs' Unjust Enrichment Claim Fails Because There Is No Such Cause of Action Under California Law**

The Amended Complaint does not indicate under which state's law Plaintiffs bring their claim for unjust enrichment, which in itself is a basis for dismissal. *See, e.g., In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 167 (E.D. Pa. 2009). To the extent that this claim, like Plaintiffs' UCL claim, is brought under California law, it must be dismissed. "Simply put, there is no cause of action in California for unjust enrichment." *Dunkel v. eBay Inc.*, No. 5:12-CV-01452, 2013 WL 415584, at \*11 (N.D. Cal. Jan. 31, 2013) (citation and quotation marks omitted). "[U]njust enrichment is not an independent claim, and hence cannot serve as an independent cause of action." *LaCourt v. Specific Media, Inc.*, No. SACV 10-1256, 2011 WL 1661532, at \*8 (C.D. Cal. Apr. 28, 2011) (citation and quotation marks omitted). Because

“California does not recognize a stand-alone cause of action for unjust enrichment,” this claim should be dismissed. *Robinson v. HSBC Bank USA*, 732 F. Supp. 2d 976, 987 (N.D. Cal. 2010) (citing cases).

**D. Plaintiffs’ Breach of Duty of Good Faith Claim Fails for Lack of Supporting Allegations**

Plaintiffs allege that Gilead breached its duty of good faith related to contracts between Gilead and the wholesalers who directly purchase Gilead’s HCV drugs. *See* AC ¶¶ 140-46. Plaintiffs further allege that they are entitled to recover for these breaches because they are third-party beneficiaries under such contracts. *See id.* ¶¶ 141, 146. Plaintiffs fail to identify under which state’s law their contract claim is brought. Again, we focus on California law because that is the state law under which Plaintiffs bring their UCL claims. In addition, as “[t]he legal elements of a breach of contract claim are substantially similar in all fifty states,” Plaintiffs’ claim would fare no better under the law of any other state. *See Robertshaw v. Pudles*, No. Civ. A. 11-7353, 2013 WL 3976284, at \*16 (E.D. Pa. Aug. 5, 2013) (citation omitted).

Plaintiffs’ theory appears to be that Gilead had some sort of contractual duty not to charge the prices specified in its contracts. *See* AC ¶¶ 143-44. This claim fails for many reasons. As a threshold matter, a plaintiff cannot use literal compliance with the obligations of a contract as evidence of “bad faith.” Plaintiffs’ contract claims also fail because Plaintiffs do not name the parties to these contracts, identify the contracts’ terms, explain precisely how Gilead supposedly breached a duty of good faith in connection with the contracts, or explain the basis for their assertion that they were intended beneficiaries of these contracts. Plaintiffs certainly do not allege that Gilead violated any particular contractual provisions requiring it to adhere to certain price levels.

Under California law, “[t]he covenant of good faith and fair dealing, implied by law in every contract, exists merely to prevent one contracting party from unfairly frustrating the other

party's right to receive the *benefits of the agreement actually made.*" *Guz v. Bechtel Nat'l, Inc.*, 8 P.3d 1089, 1110 (Cal. 2000) (emphasis in original). The covenant "cannot impose substantive duties or limits on the contracting parties beyond those incorporated in the specific terms of their agreement." *Id.* "The duty is limited to assuring compliance with the express terms of the contract, and cannot be extended to create obligations not contemplated in the contract." *McFarland v. JP Morgan Chase Bank*, No. EDCV 13-01838, 2014 WL 4119399, at \*7 (C.D. Cal. Aug. 21, 2014) (citations and quotation marks omitted). Plaintiffs' attempt to conjure out of thin air a contract law duty not to charge prices Plaintiffs do not like fails because they do not ground it in the express terms of the contracts – which, as noted, they do not allege in any fashion. *See, e.g., Harvey v. Bank of Am., N.A.*, 906 F. Supp. 2d 982, 991-92 (N.D. Cal. 2012) (dismissing claim because "Defendant's alleged conduct is not related to the contract").<sup>9</sup>

Plaintiffs' contract claim fails for the additional reason that Plaintiffs have not offered factual allegations showing that they are intended third-party beneficiaries of the contracts at issue. "[A] third party is not a beneficiary of a sales agreement merely because both contracting parties knew that the product would be resold to the third party, or to a class of which the third party was a member." *Corrugated Paper Prods., Inc. v. Longview Fibre Co.*, 868 F.2d 908, 911 (7th Cir. 1989); *see also, e.g., E. Aviation Grp., Inc. v. Airborne Express, Inc.*, 8 Cal. Rptr. 2d 355, 358 (Ct. App. 1992) (citing *Corrugated Paper* approvingly for the proposition that "when a seller knows the buyer intends to resell the goods to a third party, this does not establish that the seller intends to benefit the third party").

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<sup>9</sup> Plaintiffs utterly fail to allege the elements of a claim for breach of the covenant of good faith and fair dealing, which are: "(1) the plaintiff and the defendant entered into a contract; (2) the plaintiff did all or substantially all of the things that the contract required him to do or that he was excused from having to do; (3) all conditions required for the defendant's performance had occurred; (4) the defendant unfairly interfered with the plaintiff's right to receive the benefits of the contract; and (5) the defendant's conduct harmed the plaintiff." *Harvey*, 906 F. Supp. 2d at 991 (citation omitted).



Plaintiffs make no factual allegations at all indicating that the contracts were intended to benefit them specifically, or to benefit all actual and potential subsequent purchasers or consumers of Sovaldi and Harvoni. Instead, they make only a conclusory allegation that Gilead sold “directly to wholesalers and distributors” and then simply assert that “patients and third-party payers for these drugs were intended third-party beneficiaries of those contracts.” AC ¶ 141. These statements are merely “naked assertions devoid of further factual enhancement” and are thus insufficient to support Plaintiffs’ claim. *Iqbal*, 556 U.S. at 678 (quotation marks omitted). For this reason, too, Plaintiffs’ contract claim should be dismissed. *See, e.g., Rubio v. U.S. Bank N.A.*, No. C 13-05752, 2014 WL 2602330, at \*7 (N.D. Cal. June 10, 2014) (dismissing contract claim where plaintiff made only a conclusory allegation that it was an intended third-party beneficiary).

### **CONCLUSION**

For all of the foregoing reasons, Gilead respectfully requests that this Court dismiss the amended complaint with prejudice.

**CERTIFICATE OF SERVICE**

I, George S. Cary, do hereby certify that on this date, I caused a true and correct copy of the foregoing document to be served upon the following counsel via electronic means:

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